

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

NOVO NORDISK A/S,

Plaintiff and Counterdefendant,

v.

C.A. No. 05-645-SLR

AVENTIS PHARMACEUTICALS INC.,  
SANOFI-AVENTIS, and AVENTIS  
PHARMA DEUTSCHLAND GMBH,

Defendants and Counterplaintiffs.

**PROTECTIVE ORDER**

WHEREAS, certain documents and information may be sought, produced or exhibited by the parties to this case that contain the parties' trade secrets, technical information, financial information, competitive information, confidential research, development, or other kinds of commercially sensitive information which the party making the production deems confidential;

WHEREAS, it has been agreed by Plaintiff/Counterdefendant Novo Nordisk A/S ("Novo Nordisk") and Defendants/Counterclaimants sanofi-aventis, Aventis Pharmaceuticals, Inc. and sanofi-aventis Deutschland GmbH<sup>1</sup> (collectively "Aventis") that a Protective Order is necessary to preserve the confidentiality of these documents and information; and

WHEREAS, the Court has reviewed the terms and conditions of the Stipulated Protective Order submitted by the parties and determined that there is good cause for its entry;

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<sup>1</sup> While the Complaint names Aventis Pharma Deutschland GmbH, this entity is now known as sanofi-aventis Deutschland GmbH. Accordingly, this current title will be used in this Protective Order.

**IT IS HEREBY ORDERED:**

1. This Protective Order shall govern all documents, the information contained therein, and all other information produced or disclosed in the course of the above-captioned action (the "Proceeding"), whether revealed in a document, declaration, expert report, deposition or other testimony, discovery response, or otherwise, by any part to this Proceeding (the "Disclosing Party") to any other party (the "Receiving Party"), when such information is designated in accordance with this Protective Order. This Protective Order is binding upon the parties to the Proceeding, including such party's predecessors, successors, parents, subsidiaries, divisions and affiliated companies, companies under the direction and/or control of a party or its owner(s), and their respective attorneys, agents, representatives, officers, employees and others as set forth in this Protective Order.

2. A copy of this Protective Order shall be furnished to each third party required to produce documents or otherwise formally disclose information in response to discovery requests during the Proceeding. Such third parties may elect to avail themselves of, and agree to be bound by the terms and conditions of this Protective Order and hereby become a Disclosing Party for purposes of this Protective Order.

3. A Disclosing Party shall have the right to designate as "CONFIDENTIAL" any information that the party believes in good faith to constitute, reflect or disclose the Disclosing Party's confidential or proprietary information, where the Disclosing Party further believes in good faith that such information is not publicly known and the Disclosing Party would not normally reveal such information to third parties without an agreement to maintain it in confidence.

4. A Disclosing Party shall have the right to designate as "HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY" only information entitled to protection under Rule 26(c)(7) of the Federal Rules of Civil Procedure, the disclosure of which the Disclosing Party in good faith believes would cause harm to the competitive position of the disclosing party. Such information may include:

a. Confidential financial information, such as revenue from sales/licenses of products, net and gross revenue, profit and loss statements, earnings statements, accounts receivable/payable statements, business plans and strategic planning materials, including forecasts and marketing plans;

b. Confidential technical documents, including but not limited to, product specifications, testing and analysis, design and development documents;

c. Trade secrets, as defined by the Uniform Trade Secrets Act;

d. Customer lists and competitive market information;

e. Agreements with third parties containing sensitive business information and documents and information produced or obtained pursuant to such agreements and as to which an obligation of confidentiality attaches; and

f. unpublished patent applications and related prosecution documents.

However, information is not necessarily HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY simply by virtue of falling within one of the foregoing categories; rather the Disclosing Party must have afforded such information protections commensurate herewith to avail itself of such designation. Furthermore, the enumeration of the foregoing categories shall not be construed as suggesting or implying that information falling into one or

more of these categories is discoverable in this litigation and shall not preclude any party from properly objecting to the discovery of such information for any reason.

5. A Receiving Party that receives CONFIDENTIAL information from a Disclosing Party may only disclose that CONFIDENTIAL information to the following persons:

a. All attorneys that have entered an appearance or are employed by the same firm as attorneys who have entered an appearance, including professional, paralegal, clerical, secretarial, or other employees of the firm

b. Two (2) designated in-house attorneys of the Receiving Party that are involved in the Proceeding on behalf of the Receiving Party, provided such attorneys agree, in advance, to be bound by this Order by executing an Acknowledgment in the form attached to this Order as Exhibit A. Prior to revealing any CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information to any in-house attorney, the Receiving Party shall provide written notice, including the Exhibit A acknowledgment, to the Disclosing Party's counsel, which shall have five (5) business days to object in writing. The Receiving Party shall not disclose any CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information to the in-house attorney until the expiration of the notice period. If the Disclosing Party objects to the disclosure of CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information to the proposed attorney, it shall provide an explanation of the basis of its objection in writing. If the Receiving Party receives an objection from the Disclosing Party before the end of the notice period, the Receiving Party shall not disclose any CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information to such attorney. The Receiving Party retains the right to petition the Court for permission to disclose CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE

COUNSEL EYES ONLY information to any in-house attorney over the Disclosing Party's objection.

c. Two (2) corporate designees of the Receiving Party, provided such corporate designees who shall agree, in advance, to be bound by this Order by executing an Acknowledgement in the form attached to this Order as Exhibit A. Prior to revealing any CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information to any corporate designee, the Receiving Party shall provide written notice, including the Exhibit A acknowledgment, to the Disclosing Party's counsel, which shall have five (5) business days to object in writing. The Receiving Party shall not disclose any CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information to the corporate designee until the expiration of the notice period. If the Disclosing Party objects to the disclosure of CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information to the proposed attorney, it shall provide an explanation of the basis of its objection in writing. If the Receiving Party receives an objection from the Disclosing Party before the end of the notice period, the Receiving Party shall not disclose any CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information to such corporate designee. The Receiving Party retains the right to petition the Court for permission to disclose CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information to any corporate designee over the Disclosing Party's objection.

d. Independent consultants or experts, including their normal employees, staff and assistants who are not otherwise an employee, agent or representative of a party, and who are expressly retained by an attorney described in paragraph 5(a) to assist in preparation for

trial in this litigation, provided such consultants or experts agree, in advance, to be bound by this Order by executing an Acknowledgement in the form attached to this Order as Exhibit B. Further, a consultant's or expert's initial access to any CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information produced by another party to this Proceeding is subject to the requirements of paragraph 7 hereof.

e. Court stenographers, outside copying or exhibit preparation services, interpreters or translators whose functions require them to have access to CONFIDENTIAL information; and

f. The Court and its personnel under seal or with other suitable precautions calculated to maintain confidentiality.

6 A Receiving Party that receives HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information from a Disclosing Party may only disclose that HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information to the persons described in sub-paragraphs 5(a) and (d)-(f) and under the same restrictions described in those subparagraphs.

7. Prior to revealing any CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information to the consultant or expert, the Receiving Party's counsel shall provide written notice to the Disclosing Party's counsel, which shall then have five business days to object in writing. The written notice shall include the expert or consultant's executed Acknowledgment, curriculum vitae, a list of all the consultant's or expert's prior experience with any party to the Proceeding and any entity related to the parties, and a list of all cases in which the witness has testified as an expert at trial or by deposition within the proceeding four (4) years. The Receiving Party shall not disclose any CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information to the

consultant(s) or expert(s) until the expiration of the notice period. Consent to the disclosure of CONFIDENTIAL or HIGHLY CONFIDENTIAL--OUTSIDE COUNSEL EYES ONLY information to a proposed consultant(s) or expert(s) shall not unreasonably be withheld, and if the Disclosing Party objects to the disclosure of CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information to the proposed consultant(s) or expert(s), it shall provide an explanation of the basis of its objection in writing. If the Receiving Party receives an objection from the Disclosing Party before the end of the notice period, the Receiving Party shall not disclose any CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information to such consultant(s) or expert(s). The objecting party will have ten business days from the date that notice was provided to the Receiving Party to file a motion for a protective order with the court. If a motion is filed with the Court, no CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information should be provided to the expert or consultant until the motion is decided or the Disclosing Party agrees to permit disclosure to the expert or consultant. If a motion is not filed within ten business days of the date notice of the objection was provided to the Receiving Party, the objection is deemed to be dropped and CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information can be provided to the expert or consultant.

8. Persons receiving CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information are prohibited from disclosing it to any person, except in conformity with this Order, or such other Orders as may issue from a court of competent jurisdiction. The recipient of any CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information will maintain such information in a secure and safe area

and shall exercise the same standard of due and proper care with respect to the storage, custody, use and/or dissemination of such information as is exercised by the recipient with respect to its own proprietary information.

9 CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY material shall not be used for any purpose other than in this litigation. Specifically, but without limitation, it shall not be used in any proceedings in any other court, tribunal, or patent office (including in any opposition, reexamination Or other proceeding). The recipient of any CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information hereby agrees to subject himself/herself to jurisdiction of this Court for the purpose of any proceedings relating to the performance under, compliance with, or violation of this Order.

a. Notwithstanding the foregoing Paragraph 9, the parties agree that CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY material produced in this litigation may be used in the concurrently pending action brought by Novo Nordisk against Aventis in the U.S. International Trade Commission, Inv. No. 337-TA-572 ("the ITC action"). Such CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY material produced in this litigation may be used in the ITC action to the fullest extent as if it had been produced in the ITC action, subject to, and in accordance with, the terms of this Order. The disclosure of any material designated CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY to any attorney or firm that has not entered an appearance in the above captioned action as of the date that this protective order is filed, shall be governed by the procedure set forth in Paragraph 5(b) of this Protective Order.



10. In the event that a Receiving Party or other individual described in paragraph 5 is served with a subpoena or other judicial process demanding the production or disclosure of any CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information, the Receiving Part or individual shall provide the Receiving and Disclosing Parties with a copy of the subpoena or other judicial process within seven calendar days.

11. Parties shall designate information as "CONFIDENTIAL" or as "HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY" as follows:

a. In the case of documents, interrogatory answers, responses to requests for admission, and the information contained therein, designation shall be made by placing one of the "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY" legends on each page of any such documents. In the case of documents provided for inspection, in lieu of marking the original of a document that contains CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information prior to inspection, all information contained in such documents shall be treated as HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY until such time as the documents are produced. Any copies of such documents must be marked with one of the above legends by the Disclosing Party at the time they are supplied to the Receiving Party.

b. In the case of depositions, designation of all or a portion of the transcript that contains CONFIDENTIAL or HIGHLY CONFIDENTIAL OUTSIDE COUNSEL EYES ONLY information shall be made by a statement to such effect on the record in the course of the deposition or upon review of such transcript by the attorneys for the party to whose CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information the deponent has provided or has had access. Such review and written designation

shall occur within fourteen days after receipt of the transcript and shall include designation as to the pages of the transcript containing such designated information, if not made orally during the deposition. The transcript shall be treated as HIGHLY CONFIDENTIAL-OUTSIDE ATTORNEYS EYES ONLY until such designation is made or until expiration of fourteen days after receipt of the transcript, whichever comes first. If no designation is made, either orally during the deposition or in writing within fourteen days after receipt of the transcript, the transcript shall be considered not to contain any CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information. If during the course of a deposition, questions are asked that require the disclosure of CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information, the party whose information is to be disclosed may require that only qualified persons under paragraph 5, the deponent, the deponent's counsel, and the court reporter shall be allowed to be present during such portion of the deposition.

c. Transcripts of depositions or excerpts will not be filed with the Court unless it is necessary to do so for purposes of trial, motions for summary judgment, or other matters. If a deposition transcript or portion thereof containing CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information is filed with the Court, the transcript shall bear the appropriate legend on the caption page and on each page that contains CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information and the parties shall file such information under seal, and if necessary, shall seek leave of Court to do so.

12. A party shall not be obligated to challenge the propriety of any designation of CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY

information at the time the designation is made, and failure to do so shall not preclude a subsequent challenge to the designation. In the event that any party to this action disagrees at any stage of this action with any designation, such party shall provide written notice of its disagreement with the designation to the Disclosing Party. The parties shall first try to dispose of such dispute in good faith on an informal basis. If the dispute cannot be resolved, the party challenging the designation may request appropriate relief from the Court after a seven day period from first notice of the disagreement. The burden of proving that information has been properly designated is on the Disclosing Party.

13. a. If a party through inadvertence produces information or provides discovery that it believes is subject to a claim of attorney-client privilege or work product immunity, the Disclosing Party may give written notice to the Receiving Party that the document or thing is subject to a claim of attorney-client privilege or work product immunity and request that the document or thing be returned to the Disclosing Party. The Receiving Party shall return to the producing party such document or thing and destroy all copies. Return of the document by the Receiving Party shall not constitute an admission or concession by the Receiving Party, or permit any inference, that the returned document or thing is, in fact, properly subject to a claim of attorney-client privilege or work product immunity nor shall it foreclose any party from moving the Court for an order that such document or thing has been improperly designated or should be producible for other reasons. Moreover, the inadvertent production of a document or information subject to the attorney-client privilege or work product immunity shall not result in any waiver of the attorney-client privilege or work product immunity.

b. If the Receiving Party contests the privilege or work-product designation by the producing party, the Receiving Party shall, within five (5) business days, give the

producing party written notice of the reason for said disagreement and shall be entitled to retain one copy of the disputed document for use in resolving the dispute. The Receiving Party shall, within ten (10) business days from the initial notice by the producing party, seek an Order from the Court compelling the production of the material. If no such Order is sought, upon expiration of the ten (10) day period then all copies of the disputed document shall be returned in accordance with this paragraph. Any analyses, memoranda or notes which were internally generated based upon such inadvertently-produced information shall immediately be placed in sealed envelopes, and shall be destroyed in the event that (a) the Receiving Party does not contest that the information is privileged, or (b) the Court rules that the information is privileged. Such analyses, memoranda or notes may only be removed from the sealed envelopes and returned in the event that (a) the producing party agrees in writing that the information is not privileged, or (b) the Court rules that the information is not privileged.

c. If a party through inadvertence produces or provides discovery of any CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information without labeling or otherwise designating it under the terms of the Protective Order, the Disclosing Party may give written notice to the Receiving Party that the document, thing, or other discovery information, response, or testimony should be treated in accordance with the provisions of this Protective Order, provided that the Disclosing Party provides properly designated replacement copies. The Receiving Party must treat the documents, things, information, responses and testimony as designated from the date the notice is received. Disclosure of the mislabeled or unlabelled documents, things, information, responses, and testimony to a non-authorized person prior to receipt of the notice will not be a violation of this Protective Order. The Receiving Party will notify those persons to whom disclosure was made

of the existence of this Protective Order, that the disclosed material must thereafter be treated in accordance with this Protective Order, and have the unauthorized party provide the Disclosing Party with an undertaking in the form of Exhibit B. Upon request of the Disclosing Party, the Receiving Party will have the non-authorized person destroy all copies of the mislabeled or unlabelled documents, things, information, responses, and testimony in their possession, as well as all materials derived from such materials, and sign an oath that such documents, things, information, responses, and testimony and all materials derived from such information have been destroyed

14. Nothing in this Order shall preclude any party or its attorneys from (a) showing a document designated CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY at a deposition or other proceeding to an individual who prepared, received, or reviewed the document prior to his or her deposition, (b) using at a deposition or other proceeding of an employee or expert of a party any document that the employee's or expert's party designated CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY, or (c) disclosing or using, in any manner or for any purpose, any information or documents that the party itself has designated CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY.

15. A Party may refer to CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY in pretrial conferences before the Court, evidentiary hearings and at trial. The use of CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY at evidentiary hearings and at trial may be addressed in subsequent orders prior to such hearings and in the final pretrial order. Any Party or attorney that reasonably believes that he or she will disclose CONFIDENTIAL

INFORMATION or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY in a hearing or any other public proceeding before The Court other than at trial and evidentiary hearings shall so inform the Court and the Disclosing Party in advance of actual disclosure insofar as possible. If the Disclosing Party objects, the Disclosing Party may ask the Court to decide what precautions, if any, are appropriate to protect the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY, including how exhibits designated CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY shall be filed to maintain their confidentiality. The Disclosing Party shall not, after receiving such notice, identify to any other party, third party or affiliate of the Disclosing Party, the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY that the Receiving Party giving notice intends to use in the hearing or proceeding, or the fact that the Disclosing Party has been advised that such information may be used until after it has been disclosed at said hearing or other public proceeding.

16. Nothing herein shall prevent either Party from: (i) applying to the Court for a modification of this Stipulation should the moving Party believe that, as originally entered, the Stipulation is impairing its effort to prepare for trial; (ii) applying to the Court for further or additional protective orders; or (iii) making an agreement with the other Party to modify this Stipulation subject to the Court's approval.

17. The restrictions provided for herein shall not terminate upon the conclusion of this action but shall continue until further Order of this Court; provided, however, that this Protective Order shall not be construed: (a) to prevent any party or its attorneys from making use of information which was lawfully in its possession prior to its disclosure by the Disclosing Party;

(b) to apply to information which appears in issued patents or public records or printed publications or becomes publicly known other than as a result of disclosure by the Receiving Party, or (c) to apply to information that any party or its attorneys have, after disclosure by the producing party, lawfully obtained it from a party or third party having the right to disclose such information. The parties agree that the Court retains jurisdiction, and agree not to contest the Court's jurisdiction, to enforce the terms of this Protective Order following the formal termination of this action.

18. Within thirty (30) days of final termination of this action by entry of a final judgment from which no further appeal has been taken, all copies and samples of information or material designated CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY and any other summaries, abstracts, excerpts, indices, and/or descriptions of such material and information derived from such material that are recorded in any tangible form shall be assembled by counsel for the receiving party and returned (except for any that may be retained by the Court) to the producing party or destroyed, in which every counsel for the receiving party shall certify the destruction thereof. Within thirty days of formal termination of this action by entry of a final judgment from which no further appeal has been or can be taken, any party that has filed CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information with the Court may move for the return or destruction of the filed CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information. If any party fails to move within fourteen days for the return or destruction of CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information that it has filed, the opposing party may move for the return or destruction of the



CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information, which motion shall be considered an agreed motion.

19. The parties agree to treat all CONFIDENTIAL and HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information pursuant to the provisions of this Protective Order regardless of the source, owner, or originator of such information, and this Order shall be applicable to any third party that produces information to a party in this action that is designated by such third party as containing CONFIDENTIAL or HIGHLY CONFIDENTIAL-OUTSIDE COUNSEL EYES ONLY information.

20. This order is without prejudice to the right of any party to seek relief from the Court upon good cause shown from any of the provisions contained herein.

Dated:

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Honorable Sue L. Robinson  
UNITED STATES DISTRICT JUDGE

/s/ Steven J. Balick (#2403)  
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